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DEC 2 6 2007

KARL STORZ ENDOSCOPY

510(k) SUMMARY

Sponsor/Submitter: Karl Storz Endoscopy – America, Inc.
600 Corporate Pointe
Culver City, CA 90230-7600
Phone: (310) 338-8100
Fax: (310) 410-5519

Contact Person: Crystal Dizol
Regulatory Affairs Associate
Email: cdizol@ksea.com

Date of Submission: September 24, 2007

Device Trade Name: Storz MODULITH® Lithotripter SLX-F2 F180

Common Name: Extracorporeal Shock Wave Lithotripter

Classification Name: Lithotripter, Extracorporeal Shock-Wave, Urological

Regulation Number: 21 CFR 876.5990

Product Code: LNS

Predicate Device(s): Storz MODULITH Lithotripter SLX-F2 (K040476)
Medispec Econolith EM1000 (K063504)

Device Description: The Storz MODULITH® Lithotripter SLX-F2 F180 is an Extracorporeal Shock Wave Lithotripter Device. It generates shock waves that are focused onto a kidney or ureteral stone so that the stone fragments can be passed with the patient's urine.

Indications for Use: The Storz MODULITH® Lithotripter SLX-F2 F180 is indicated for use in the noninvasive fragmentation of urinary calculi in the kidney and upper ureter.

Technological Characteristics: The Storz MODULITH® Lithotripter SLX-F2 F180 and its predicate devices generate shock waves using electromagnetically repelled membranes. The shock waves are focused onto the stone by a parabolic reflector dish, and are transferred to the patient's body via contact with a water-filled rubber cushion.

Summary of Substantial Equivalence: The Storz MODULITH® Lithotripter SLX-F2 F180 is substantially equivalent to the predicate devices since the intended uses and technological characteristics are similar. The minor differences between the Storz MODULITH® Lithotripter SLX-F2 and the predicate devices raise no new issues of safety and effectiveness, as these design differences have no affect on the performance, function or intended use of the devices.

Att: Substantial Equivalence Table for Storz MODULITH® Lithotripter SLX-F2 F180

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SUBSTANTIAL EQUIVALENCE TABLE FOR STORZ MODULITH® SLX-F2 F180

Manufacturer	*Storz Medical AG*	*Storz Medical AG*	*Medispec, Ltd.*
Trade/Proprietary Name	*MODULITH® SLX-F2 F180*	*MODULITH® SLX-F2*	*Econolith™ EM1000*
510(k) Number	Not Yet Assigned	K040476	K063504
Shock wave generator	Electromagnetic	Electromagnetic	Electromagnetic
Diameter of source	300 mm	300 mm	Unavailable
Treatment depth	180 mm	165 mm	145-175 mm
Focal size (typical)	F1: 2 x 24 mm F2: 4.7 x 39 mm	F1: 2 x 20 mm F2: 4.8 x 36 mm	11 x 175 mm
Peak-positive pressure, Min/Max (MPa)	F1: 18 – 107 F2: 15 – 36	F1: 18 – 107 F2: 16 – 44	9.8 – 41.6
Focal energy, Min/Max (MPa)	F1: 1.9 – 2.1 F2: 3.8 – 4.0	F1: 2.2 – 2.5 F2: 4.3 – 5.5	Unavailable
Number of Energy Levels	26	26	Unavailable
Intended Use	For use in the noninvasive fragmentation of urinary calculi in the kidney and upper ureter.	For use in the noninvasive fragmentation of urinary calculi in the kidney and upper ureter.	For use in non-invasive fragmentation of upper urinary tract stones, to include urinary stones located in the kidney (renal pelvis and renal calyces) and upper ureter.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 6 2007

Crystal Dizol
Regulatory Affairs Associate
Karl Storz Endoscopy-America, Inc.
600 Corporate Pointe 5th Floor
Culver City, CA 90230-7600

Re: K072788
Trade/Device Name: Storz MODULITH® Lithotripter SLX-F2 F180
Regulation Number: 21 CFR 876.5990
Regulation Name: Extracorporeal shock wave lithotripter
Regulatory Class: Class II
Product Code: LNS
Dated: September 24, 2007
Received: October 1, 2007

Dear Ms. Dizol:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1796, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K072788

Device Name: Storz MODULITH® Lithotripter SLX-F2 F180

Indications for Use: The Storz MODULITH® Lithotripter SLX-F2 F180 is intended for use in the noninvasive fragmentation of urinary calculi in the kidney and upper ureter.

Prescription Use: ✓ AND/OR Over-The-Counter Use: _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072788